PMA Monthly approvals from 6/1/2016 to 6/30/2016

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150024	06/14/2016	PMAO - PMA Origi	ASPIREASSIST	ASPIRE BARIATRICS INC	Approval for the AspireAssist® is intended to assist in weight reduction of obese patients. It is indicated for use in adults aged 22 or older with a Body Mass Index (BMI) of 35.0-55.0 kg/m2 who have failed to achieve and maintain weight loss with non-surgical weight loss therapy. The AspireAssist is intended for a long-term duration of use in conjunction with lifestyle therapy and continuous medical monitoring.
P150029	06/17/2016	PMAO - PMA Origi	IPRO2 CGM SYSTEM WITH ENLITE SENSOR	MEDTRONIC MINIMED	Approval for the iPro2 System. This device is indicated for: The iPro2 Recorder is to be used with either Enlite sensor or Sof-Sensor and is intended to continuously record interstitial glucose levels in persons with diabetes mellitus. This information is intended to supplement, not replace, blood glucose information obtained using a standard home glucose-monitoring device. The information collected by the iPro2 Recorder may be uploaded to a computer (with Internet access) and reviewed by healthcare professionals. This information may allow identification of patterns of glucose level excursions above or below the desired range, facilitating therapy adjustments which may minimize these excursions. The iPro2 system: 1) Is intended for prescription use only; 2) Does not allow data to be made available directly to patients in real time; 3) Provides data that will be available for review by physicians after the recording interval (up to 144 hours); 4) Is intended for occasional rather than everyday use; and 5) Is to be used only as a supplement, and not a replacement for, standard invasive measurement.
P150034	06/29/2016	PMAO - PMA Origi	RAINDROP NEAR VISION INLAY	REVISION OPTICS, INCORPORATED	Approval for the Raindrop® Near Vision Inlay. This device is indicated for intrastromal implantation to improve near vision in the non-dominant eye of phakic, presbyopic patients, 41 to 65 years of age, who have manifest refractive spherical equivalent of (MRSE) +1.00 diopters (D) to -0.50 D with less than or equal to 0.75 D of refractive cylinder, who do not require correction for clear distance vision, but who do require near correction of +1.50 D to +2.50 D of reading add.

P150047	06/01/2016	PMAO - PMA Origi	COBAS EGFR MUTATION TEST V2	ROCHE MOLECULAR SYSTEMS, INC.	Approval for the cobas® EGFR Mutation Test v2 is a real-time PCR test for the qualitative detection of defined mutations of the epidermal growth factor receptor (EGFR) gene in non-small cell lung cancer (NSCLC) patients. Defined EGFR mutations are detected using DNA isolated from formalin-fixed paraffin-embedded tumor tissue (FFPET) or circulating-free tumor DNA (cfDNA) from plasma derived from EDTA anti-coagulated peripheral whole blood. The test is indicated as a companion diagnostic to aid in selecting NSCLC patients for treatment with the targeted therapies listed in Table 1 below in accordance with the approved therapeutic product labeling. Table 1 Drug FFPET Plasma TARCEVA® (erlotinib) Exon 19 deletions and L858R Exon 19 deletions and L858R TAGRISSO (osimertinib) T790M Patients with positive cobas® EGFR Mutation Test v2 test results using plasma specimens for the presence of EGFR exon 19 deletions or L858R mutations are eligible for treatment with TARCEVA® (erlotinib). Patients who are negative for these mutations by this test should be reflexed to routine biopsy and testing for EGFR mutations with the FFPET sample type. Drug safety and efficacy have not been established for the EGFR mutations listed in Table 2 below that are also detected by the cobas® EGFR Mutation Test v2. Table 2 Drug FFPET Plasma TARCEVA® (erlotinib) G719X, exon 20 insertions, T790M, S768I and L861Q G719X, exon 20 insertions, T790M, S768I and L861Q TAGRISSO (osimertinib) G719X, exon 19 deletions, L858R, exon 20 insertions, S768I, and L861Q G719X, exon 19 deletions, L858R, exon 20 insertions, T790M, S768I, and L861Q For manual sample preparation, FFPET specimens are processed using the cobas® DNA Sample Preparation Kit and plasma specimens are processed using the cobas® cfDNA Sample Preparation Kit. The cobas z 480 analyzer is used for automated amplification and detection.

Total: 4

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P810031/S056	06/14/2016	N - Normal 180 Day	HEALON SODIUM HYALURONATE OPHTHALMIC VISCOELASTIC DEVICES (OVD), HEALON5 SODIUM HYALURONATE OPHTHALMIC VISCOELASTIC DEVI	ABBOTT MEDICAL OPTICS INC	Approval for an alternative secondary blister tray packaging configuration called drop pack for AMOs family of Healon® OVDs that incorporates a transition Tyvek® lid manufactured using DuPonts flash-spinning process.
P880086/S272	06/28/2016	R - Real-Time Proc	ACCENT, IDENTITY, VERITY, VICTORY AND ZEPHYR PACEMAKERS	ST. JUDE MEDICAL, INC.	Approval for Merlin PCS Model 3330 v22.0.1 Software.
P890003/S355	06/16/2016	R - Real-Time Proc	MYCARELINK PATIENT MONITOR 24950	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for modifications to the Telemetry M Module.
P910023/S371	06/28/2016	R - Real-Time Proc	ELLIPSE/FORTIFY ASSURA FAMILY OF ICDS	St. Jude Medical	Approval for Merlin PCS Model 3330 v22.0.1 Software.
P920047/S091	06/23/2016	Y - 135 Review Tra	BLAZER II, BLAZER II HTD, BLAZER PRIME HTD	BOSTON SCIENTIFIC CORP.	Approval for the addition of Lake Region Medical as an alternate vendor for ring electrode part numbers 150493, 14295-001, and 90414197-01.
P950029/S105	06/24/2016	N - Normal 180 Day	REPLY DR, REPLY SR, ESPRIT DR, ESPRIT SR	SORIN CRM USA, INC.	Approval for hardware modifications to the REPLY/ESPRIT pacemaker platform.

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P950037/S156	06/08/2016	N - Normal 180 Day	SIELLO S 45, SIELLO S 53,SIELLO S 60,SOLIA S45,SOLIA S 53,SOLIA S60	BIOTRONIK, INC.	Approval for Siello S and Solia S pacing leads.
P970013/S069	06/28/2016	R - Real-Time Proc	MICRONY PACEMAKERS	ST. JUDE MEDICAL, INC.	Approval for Merlin PCS Model 3330 v22.0.1 Software.
P970051/S140	06/20/2016	N - Normal 180 Day	NUCLEUS COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for the optional acoustic component amplifies low frequency sound, and sends it into the ear canal. The acoustic component is intended to provide access to these low frequency sounds for some Cochlear Nucleus implant recipients. The acoustic component is indicated for recipients of traditional Cochlear Nucleus implants with unaided air conduction thresholds less than or equal to 85 dB HL between 125 Hz and 2000 Hz following surgery. The acoustic component should only be used when behavioural audiometric thresholds can be obtained and the recipient can provide feedback regarding sound quality. Speech perception testing should be completed before and after fitting with the acoustic component to ensure that the recipient performs as well, if not better, with the acoustic component than without it.
P980003/S066	06/23/2016	Y - 135 Review Tra	CHILLI COOLED RF ABLATION SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for the addition of Lake Region Medical as an alternate vendor for the ring electrode component.
P980016/S587	06/16/2016	R - Real-Time Proc	EVERA MRI, EVERA S DR, EVERA S VR, EVERA XT DR, EVERA XT VR, VISIA AF MRI VR, VISIA AF VR ICD.	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for modifications to the Telemetry M Module.
P980022/S183	06/03/2016	Y - 135 Review Tra	PARADIGM REAL-TIME INSULIN PUMP, PARADIGM REAL-TIME REVEL INSULIN PUMP	MEDTRONIC MINIMED	Approval for changes to the pump case drive support cap assembly process and the automated adhesive dispensing process used in the pump case manufacturing process of the Paradigm family of insulin pumps (models 5xx and 7xx). Paradigm insulin pumps are components of the Paradigm REAL-Time System, Paradigm REAL-Time Revel System and the MiniMed 530G System.
P990021/S003	06/28/2016	N - Normal 180 Day	PHOTOFRIN 630 PDT LASER	CONCORDIA LABORATORIES, INC	Approval for the PHOTOFRIN 630 PDT Laser manufactured by Modulight, Inc located in Tampere, Finland.
P990040/S022	06/03/2016	N - Normal 180 Day	TRUFILL N-BUTYL CYANOACRYLATE LIQUID EMBOLIC SYSTEM	CODMAN & SHURTLEFF, INC.	Approval for modified acceptance criteria for n-BCA purity and a control limit for n-BCA dimers.

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P000015/S012	06/13/2016	N - Normal 180 Day	NUCLEUS ABI541 AUDITORY BRAINSTEM IMPLANT	COCHLEAR AMERICAS	Approval for the Nucleus ABI541 Auditory Brainstem Implant, a modification to the existing ABI24M device, which is intended to restore a level of auditory sensation via electrical stimulation of the cochlear nucleus in individuals 12 years of age or older who have been diagnosed with Neurofibromatosis Type 2 (NF2). Implantation may occur during first or second side tumor removal or in patients with previously removed acoustic tumors bilaterally. Because the surgical procedure for tumor excision and electrode placement eliminates residual hearing, preoperative audiological criteria are not relevant. This supplement also requested approval for a new bodyworn battery pack compatible with the Nucleus 6 Sound Processor, and the ability to program ABI541 recipients using the Advanced Combination Encoder (ACE) sound coding strategy.
P010012/S416	06/09/2016	R - Real-Time Proc	ACUITY X4 (STRAIGHT,SPIRAL S, SPIRAL L) STEROID-ELUTING, CORONARY VENOUS, QUADRIPOLAR ACE/SENSE LEADS	BOSTON SCIENTIFIC CORP.	Approval for a shelf-life extension to 18 months.
P010030/S073	06/14/2016	R - Real-Time Proc	WEARABLE CARDIOVERTER DEFIBRILLATOR (WCD) 2000 "LIFEVEST"	ZOLL MANUFACTURING CORPORATION	Approval for modifications to current software (bug fixes, improvements, background noise detection feature).
P010031/S547	06/16/2016	R - Real-Time Proc	AMPLIA MRI, AMPLIA MRI QUAD, BRAVA, BRAVA QUAD, COMPIA MRI,COMPIA MRI QUAD, VIVA QUAD S, VIVA QUAD XT, VIVA S, VIVA XT CRT-D.	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for modifications to the Telemetry M Module.
P020004/S126	06/13/2016	R - Real-Time Proc	EXCLUDER BIFURCATED ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Approval for an alternate colorant to be used for components of the Gore EXCLUDER AAA Endoprosthesis SIM-PULL Delivery System.
P020018/S056	06/03/2016	S - Special CBE	ZENITH AAA ENDOVASCULAR GRAFT AND H&L-B ONE-SHOT INTRODUCTINO SYSTEM	COOK, INC.	Approval to change the in-process sampling for endotoxin testing.
P020025/S087	06/23/2016	Y - 135 Review Tra	BLAZER II XP, BLAZER PRIME XP, INTELLATIP MIFI XP, INTELLANAV XP, INTELLANAV MIFI XP	BOSTON SCIENTIFIC	Approval for the addition of Lake Region Medical as an alternate vendor for the ring electrode component.
P020036/S037	06/09/2016	R - Real-Time Proc	S.M.A.R.T. CONTROL NITINOL STENT SYSTEM	CORDIS CORP.	Approval for changes to the MR labeling.

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P030017/S250	06/08/2016	R - Real-Time Proc	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for the addition of an alternate qualified supplier for the Coil Connector that is used in the assembly of the Precision Novi Implantable Pulse Generator.
P030017/S251	06/07/2016	R - Real-Time Proc	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for adding an alternate qualified supplier for the Coil Connector that is used in the assembly of the Precision M1 and M8 Adaptors.
P030022/S033	06/08/2016	O - Normal 180 Day	ANTHOLOGY FEMORAL STEMS	SMITH & NEPHEW, INC.	Approval for a manufacturing site located at Orchid Detroit 23149 Commerce Drive, Farmington Hills, MI 48335.
P030035/S146	06/28/2016	R - Real-Time Proc	ANTHEM AND FRONTIER II CRT-P'S	ST. JUDE MEDICAL, INC.	Approval for Merlin PCS Model 3330 v22.0.1 Software.
P030054/S302	06/28/2016	R - Real-Time Proc	QUADRA ASSURA/UNIFY ASSURA FAMILY OF CRT-DS	St. Jude Medical	Approval for Merlin PCS Model 3330 v22.0.1 Software.
P040003/S017	06/27/2016	R - Real-Time Proc	EXABLATE 2000 SYSTEM	INSIGHTEC, LTD	Approval for updates to the software to change the operating system and fix minor software defects.
P040024/S090	06/01/2016	Y - 135 Review Tra	RESTYLANE, RESTYLANE-L, RESTYLANE LYFT, RESTYLANE SILK, PERLANE	GALDERMA LABORATORIES L.P	Approval for an additional control step for the filtration of lidocaine.
P050023/S095	06/16/2016	O - Normal 180 Day	PROMRI ICD SYSTEM	BIOTRONIK, INC.	Approval for the ProMRI Full Body Scan ICD System of the post-approval study protocol.
P050023/S098	06/08/2016	R - Real-Time Proc	CARDIOMESSENGER SMART	BIOTRONIK, INC.	Approval for a minor firmware update.
P050037/S066	06/03/2016	Y - 135 Review Tra	RADIESSE	MERZ NORTH AMERICA, INC	Approval for changes to CaHA particle lot size and extrusion force testing.
P050037/S068	06/03/2016	Y - 135 Review Tra	RADIESSE, RADIESSE LOW VISCOSITY	MERZ NORTH AMERICA, INC	Approval for three changes to the calcium hydroxylapatite particle manufacturing process and one change to the sodium carboxymethylcellulose sampling process.

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P050037/S070	06/02/2016	Y - 135 Review Tra	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Approval for relocation of an automatic packing line within the approved facility.
P050052/S077	06/03/2016	Y - 135 Review Tra	RADIESSE, RADIESSE(+)	MERZ NORTH AMERICA, INC	Approval for changes to CaHA particle lot size and extrusion force testing.
P050052/S079	06/03/2016	Y - 135 Review Tra	RADIESSE LOW VISCOSITY, RADIESSE (+)	MERZ NORTH AMERICA, INC	Approval for three changes to the calcium hydroxylapatite particle manufacturing process and one change to the sodium carboxymethylcellulose sampling process.
P050052/S082	06/02/2016	Y - 135 Review Tra	RADIESSE & RADIESSE (+) LIDOCAINE DERMAL FILLER	MERZ NORTH AMERICA, INC	Approval for relocation of an automatic packing line within the approved facility.
P060040/S052	06/17/2016	R - Real-Time Proc	THORATEC HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORP.	Approval for revisions to the user interface of the HeartMate II (HM II) LVAS System Monitor.
P100006/S004	06/23/2016	O - Normal 180 Day	AUGMENT BONE GRAFT	BIOMIMETIC THERAPEUTICS,LLC	Approval for a manufacturing site located at BioMimetic Therapeutics, Inc. (BMTI), 389 Nichol Mill Lane, Franklin, Tennessee, for final kit assembly and packaging.
P100047/S075	06/23/2016	S - Special CBE	HEARTWARE LEFT VENTRICULAR ASSIST SYSTEM	HEARTWARE, INC.	Approval for the manufacturing process updates for the HeartWare Left Ventricular Assist Device Controller.
P110004/S017	06/24/2016	O - Normal 180 Day	NIRXCELL COCR CORONARY STENT ON RX SYSTEM (NIRXCELL STENT SYSTEM)	MEDINOL LTD.	Approval of the following changes to the post-approval study for the device: revisions to the exclusion criteria and clarification of the serious adverse event definition.
P110039/S005	06/27/2016	R - Real-Time Proc	EXABLATE	INSIGHTEC	Approval for updates to the software to change the operating system and fix minor software defects.
P120010/S076	06/03/2016	Y - 135 Review Tra	MINIMED 530G INSULIN PUMP	MEDTRONIC INC.	Approval for changes to the pump case drive support cap assembly process and the automated adhesive dispensing process used in the pump case manufacturing process of the Paradigm family of insulin pumps (models 5xx and 7xx). Paradigm insulin pumps are components of the Paradigm REAL-Time System, Paradigm REAL-Time Revel System and the MiniMed 530G System.
P130007/S011	06/16/2016	R - Real-Time Proc	ANIMAS VIBE SYSTEM	ANIMAS CORP.	Approval for a design change to the T1 inductor of the main board used in the Animas Vibe System.

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P130007/S012	06/30/2016	R - Real-Time Proc	ANIMAS VIBE SYSTEM	ANIMAS CORP.	Approval for design and material changes to the Force Sensor Flex assembly and Battery Cap O-Ring used in the Animas Vibe pump.
P130008/S009	06/02/2016	N - Normal 180 Day	INSPIRE UPPER AIRWAY STIMULATION THERAPY SYSTEM	INSPIRE MEDICAL SYSTEMS	Approval for the Model 2500 Sleep Remote (i.e. patient programmer).
P130008/S010	06/01/2016	O - Normal 180 Day	INSPIRE II UPPER AIRWAY STIMULATION SYSTEM	INSPIRE MEDICAL SYSTEMS	Approval of the following changes to the post-approval study for the device: revisions to the protocol to increase the enrollment rate.
P130009/S060	06/27/2016	S - Special CBE	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval for the addition of a new inspection step to the final inspection process for the Edwards Expandable Introducer Sheath Set.
P130013/S010	06/28/2016	R - Real-Time Proc	WATCHMAN LEFT ATRIAL APPENDAGE CLOSURE (LAAC) DEVICE	BOSTON SCIENTIFIC CORP.	Approval of an alternate material and supplier for the suture component of the device.
P130019/S009	06/27/2016	O - Normal 180 Day	MAESTRO RECHARGEABLE SYSTEM	ENTEROMEDICS INC.	Approval of an amended protocol for the ODE Lead PMA Post-Approval Study.
P130022/S005	06/14/2016	R - Real-Time Proc	NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Approval to update the design of the charging coil to eliminate the termination wraps at the end of the charging coil.
P130024/S011	06/28/2016	O - Normal 180 Day	LUTONIX DRUG COATED BALLOON PTA CATHETER	LUTONIX	Approval for a labeling update to include 24 month clinical results.
P130028/S004	06/10/2016	R - Real-Time Proc	ALGOVITA SPINAL CORD STIMULATION SYSTEM	ALGOSTIM, LLC	Approval for the following changes to the 8- and 12-electrode lead extensions for your Algovita Spinal Cord Stimulation System: 1) Decreasing your design specifications for the maximum insertion/withdrawal force from 2.0 lbf to 1.5 lbf; 2) Revising your supplier shipping requirements for the spring system connector subassembly to have the subassembly shipped while threaded on a core pin; and 3) Elimination of the distal end strain relief.
P140020/S006	06/17/2016	R - Real-Time Proc	BRACANALYSIS CDX	MYRIAD GENETIC LABORATORIES	Approval to remove the Variant Viewer application tool from the BRACAnalysis CDx device.

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P140020/S007	06/17/2016	R - Real-Time Proc	BRACANALYSIS CDX	MYRIAD GENETIC LABORATORIES	Approval to remove the DNA extraction system from serialization, and to remove non-critical instruments from the specified device components.
P150003/S013	06/17/2016	R - Real-Time Proc	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM (MONORAIL)	Boston Scientific Corporation	Approval for a change to the stent protector, carrier tube clip, and addition of a graphic insert to the packaging.
P150005/S007	06/23/2016	Y - 135 Review Tra	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Approval for the addition of Lake Region Medical as an alternate vendor for the ring electrode component.
P150022/S001	06/10/2016	R - Real-Time Proc	CLOSER VASCULAR SEALING SYSTEM	REX MEDICAL, L.P.	Approval for the use of the modified Arrow sheath.

Total: 58

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S037	06/17/2016	X - 30-Day Notice	SURGICEL FAMILY OF ABSORBABLE HEMOSTAT	ETHICON, INC.	Existing supplier of critical components would like to qualify a site change to consolidate existing manufacturing processes and equipment.
N970003/S190	06/20/2016	X - 30-Day Notice	INGENIO¿ 2 PACEMAKERS; ALTRUA 2¿ MODELS: S701, S702, S722; ESSENTIO ¿ MODELS: L100, L101, L121; PROPONENT ¿ MODELS: L200, L201, L221; ACCOLADE ¿ MODELS: L300, L301, L321	BOSTON SCIENTIFIC CORP.	Remove the final finish wetblast manufacturing process step.
N970012/S116	06/30/2016	X - 30-Day Notice	AMS 700 INFLATABLE PENILE PROSTHESIS (IPP) WITH INHIBIZONE TREATMENT	BOSTON SCIENTIFIC CORP.	Changes to the components and cleaning method of the equipment for the InhibiZone production line.
P810006/S072	06/22/2016	X - 30-Day Notice	COLLASTAT ABSORBABLE COLLAGEN HEMOSTATIC AGENTS	INTEGRA LIFESCIENCES CORPORATION	Create a new procedure, Cutting and Inspection Procedure - ACS, for the cutting and inspection of Absorbable Collagen Sponge (ACS)-(EU) used as a component of the InductOs marketed in the European Union (EU) product in room 304, 105 Morgan Lane, Plainsboro, New Jersey. This procedure directs operators to cull out and reject any cut collagen sponge that has visible foreign matter embedded in or on the surface of the collagen sponge during the inspection process. In addition, a procedure, Packaging of ACS Sponge 3¿x 4¿ or 1¿x 2¿ 6-Pack or 1¿x 2¿ 2-Packs on the Belco Sealer # 2, has been revised to direct operators to reject packaged product that has visible foreign matter on the product or inside the primary or secondary packaging.
P810031/S057	06/28/2016	X - 30-Day Notice	SODIUM HYALURONATE OPHTHALMIC VISCOELASTIC DEVICES (OVD), HEALON, HEALON GV, HEALON ULTIMATE DUAL PACK, AND HEALON DUET DUAL PACK PRODUCTS	ABBOTT MEDICAL OPTICS INC	Change in shelf life due to the use of a new detergent in the manufacturing process.
P830055/S170	06/03/2016	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Addition of part identification and traceability components throughout the manufacturing process.
P830060/S081	06/23/2016	X - 30-Day Notice	VENTAK ICD FAMILY	BOSTON SCIENTIFIC	Alternate sterilization recipe and addition of a new sterilization release mechanism.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P840001/S328	06/29/2016	X - 30-Day Notice	RESTORE, ITREL, SYNERGY SPINAL CORD STIMULATION SYSTEMS.	MEDTRONIC NEUROMODULATION	Implement a rework process for filling bubbles within the medical adhesive on the Implantable Pulse Generator (IPG) connector blocks.
P840039/S061	06/15/2016	X - 30-Day Notice	PMMA ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENSES	BAUSCH & LOMB, INC.	Add an alternate packaging component supplier for the PMMA Absorbing Anterior Chamber Intraocular Lenses, Models S122UV and L122UV and PMMA Absorbing Posterior Chamber Intraocular Lenses, Model EZE-60.
P850010/S071	06/22/2016	X - 30-Day Notice	HELISTAT,HELITENE ABSORBABLE COLLAGEN HEMOSTATIC AGENTS	INTEGRA LIFESCIENCES CORPORATION	Create a new procedure, Cutting and Inspection Procedure - ACS, for the cutting and inspection of Absorbable Collagen Sponge (ACS)-(EU) used as a component of the InductOs marketed in the European Union (EU) product in room 304, 105 Morgan Lane, Plainsboro, New Jersey. This procedure directs operators to cull out and reject any cut collagen sponge that has visible foreign matter embedded in or on the surface of the collagen sponge during the inspection process. In addition, a procedure, Packaging of ACS Sponge 3¿x 4¿ or 1¿x 2¿ 6-Pack or 1¿x 2¿ 2-Packs on the Belco Sealer # 2, has been revised to direct operators to reject packaged product that has visible foreign matter on the product or inside the primary or secondary packaging.
P860057/S149	06/23/2016	X - 30-Day Notice	CARPENTIER-EDWARDS PERIMOUNT PERICARDIAL AORTIC AND MITRAL BIOPROSTHESIS	EDWARDS LIFESCIENCES, LLC.	Additional laser cutting system to cut fabric components during manufacturing.
P870072/S062	06/14/2016	X - 30-Day Notice	THORATEC(R) VENTRICULAR ASSIST DEVICE (VAD) SYSTEM	THORATEC LABORATORIES CORP.	Implementation of a new facility (same supplier) to provide the Battery Pack Assembly TLC II for the Thoratec Ventricular Assist Device (VAD).
P880090/S029	06/15/2016	X - 30-Day Notice	PMMA ABSORBING ANTERIOR CHAMBER INTRAOCULAR LENSES	BAUSCH & LOMB, INC.	Add an alternate packaging component supplier for the PMMA Absorbing Anterior Chamber Intraocular Lenses, Models S122UV and L122UV and PMMA Absorbing Posterior Chamber Intraocular Lenses, Model EZE-60.
P910001/S086	06/16/2016	X - 30-Day Notice	EXCIMER LASER CORONARY ATHERECTOMY CATHETER	SPECTRANETICS CORP.	Addition of a manufacturing tool used in the fiber trimming process.
P910056/S023	06/23/2016	X - 30-Day Notice	ENVISTA HYDROPHOBIC ACRYLIC INTRAOCULAR LENS, MODEL MX60	BAUSCH & LOMB, INC.	Addition of an alternative Fourier Transform Infrared Spectroscopy (FTIR) laboratory.
P910061/S023	06/27/2016	X - 30-Day Notice	SOFPORT POSTERIOR CHAMBER INTRAOCULAR LENSES	BAUSCH & LOMB	Addition of an alternate packaging component supplier for the Sofport Posterior Chamber Intraocular Lenses.
P910073/S135	06/23/2016	X - 30-Day Notice	ENDOTAK LEAD SYSTEM	BOSTON SCIENTIFIC	Alternate sterilization recipe and addition of a new sterilization release mechanism.
P910077/S153	06/23/2016	X - 30-Day Notice	VENTAK PRX AND VENTAK MINI ICD FAMILIES	BOSTON SCIENTIFIC	Alternate sterilization recipe and addition of a new sterilization release mechanism.
P920015/S180	06/17/2016	X - 30-Day Notice	SPRINT QUATTRO LEAD	MEDTRONIC INC.	Change to the adhesive mixture process used during lead backfill.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P930035/S028	06/23/2016	X - 30-Day Notice	VENTAK(R) P2 ICD FAMILY	BOSTON SCIENTIFIC	Alternate sterilization recipe and addition of a new sterilization release mechanism.
P940008/S032	06/23/2016	X - 30-Day Notice	RES-Q AND RES-Q MICRON ICD AND ICD LEAD FAMILY	BOSTON SCIENTIFIC	Alternate sterilization recipe and addition of a new sterilization release mechanism.
P950001/S028	06/23/2016	X - 30-Day Notice	SELUTE PACING LEAD FAMILY	BOSTON SCIENTIFIC	Alternate sterilization recipe and addition of a new sterilization release mechanism.
P950009/S021	06/17/2016	X - 30-Day Notice	BD FOCALPOINT GS IMAGING SYSTEM	BD DIAGNOSTICS	Changes to the printed circuit board reported in this supplement in conjunction with the changes to replace VIC chip and change of manufacturing supplier qualify.
P950020/S073	06/09/2016	X - 30-Day Notice	FLEXTOME CUTTING BALLOON MICROSURGICAL DILITATION DEVICE	BOSTON SCIENTIFIC CORP.	Implement changes to the balloon protector component manufacturing of the subject device.
P950029/S110	06/22/2016	X - 30-Day Notice	REPLY SR, REPLY DR, ESPRIT SR, ESPRIT DR PACEMAKERS	SORIN GROUP- CRM	Use of Automated Optical Inspection in a portion of the final electrical assembly visual inspection.
P950037/S163	06/24/2016	X - 30-Day Notice	VARIOUS MODELS OF EVIA, ENTOVIS, ESTELLA, EFFECTA, ECURO, ELUNA, ETRINSA, EPYRA PULSE GENERATOR FAMILIES	BIOTRONIK, INC.	Alternate supplier of the epoxy resin used in the device headers.
P960004/S076	06/23/2016	X - 30-Day Notice	THINLINE/FINELINE FAMILY OF ENDOCARDIAL PACING LEADS	BOSTON SCIENTIFIC	Alternate sterilization recipe and addition of a new sterilization release mechanism.
P960006/S046	06/23/2016	X - 30-Day Notice	SWEET TIP RX, SWEET PICOTIP RX, AND FLEXTEND PACING LEAD FAMILIES	BOSTON SCIENTIFIC	Alternate sterilization recipe and addition of a new sterilization release mechanism.
P960009/S251	06/29/2016	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Implement a rework process for filling bubbles within the medical adhesive on the Implantable Pulse Generator (IPG) connector blocks.

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P960016/S066	06/29/2016	X - 30-Day Notice	LIVEWIRE TC ABLATION CATHETER AND SAFIRE BI-DIRECTIONAL ABLATION CATHETER	St. Jude Medical	Change to the current Livewire TC and Safire Bi-Directional in-process tensile test frequency for catheter ring brazing and catheter tip brazing.
P960028/S039	06/27/2016	X - 30-Day Notice	REZOOM MULTIFOCAL INTRAOCULAR LENS	ABBOTT MEDICAL OPTICS INC	Alternate sheet casting process.
P960040/S373	06/20/2016	X - 30-Day Notice	ORIGEN ¿ EL ICD: D050, D051, D052, D053; INOGEN ¿ EL ICD: D140, D141, D142, D143; DYNAGEN ¿ EL ICD: D150, D151, D152, D153; ORIGEN ¿ MINI ICD: D000, D001, D002, D003; INOGEN ¿ MINI ICD: D010, D011, D012, D013; DYNAGEN ¿ MINI ICD: D020, D021, D022, D023	BOSTON SCIENTIFIC	Remove the final finish wetblast manufacturing process step.
P960042/S054	06/16/2016	X - 30-Day Notice	SPECTRANETICS LASER SHEATHS	SPECTRANETICS CORP.	Addition of a manufacturing tool used in the fiber trimming process.
P970003/S199	06/08/2016	X - 30-Day Notice	PULSE MODEL 102, DEMIPULSE MODEL 103, ASPIREHC MODEL 105, ASPIRESR MODEL 106 GENERATOR.	CYBERONICS, INC.	Use of a new resistance welder during the spot welding of anchor tabs onto Model 102, 103, 105 and 106 generator-cans of the VNS Therapy Systems.
P970004/S213	06/07/2016	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM (URINARY)	MEDTRONIC NEUROMODULATION	Changes related to the under bump metallization (UBM) for the telemetry M module subcomponent of the impacted external device (model 3537).
P970018/S034	06/17/2016	X - 30-Day Notice	BD TOTALYS SLIDEPREP	BD DIAGNOSTIC SYSTEMS	Manufacturing site change.
P970029/S029	06/21/2016	X - 30-Day Notice	TMR HOLMIUM LASER SYSTEM	CRYOLIFE, INC.	Change to the frequency of the bioburden assessments, from quarterly to annually, for the SoloGrip III and PEARL 5.0 Handpieces.
P970029/S030	06/23/2016	X - 30-Day Notice	TMR HOLMIUM LASER SYSTEM	CRYOLIFE, INC.	Adding an incoming visual inspection to be conducted after sterilization and before shipping of the laser handpieces.

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P970051/S146	06/23/2016	X - 30-Day Notice	NUCLEUS COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Addition of a welding rework process to the existing welding process joining the top shell to the brazed chassis.
P980016/S590	06/07/2016	X - 30-Day Notice	EVERA MRI ICD, VISTA AF MRI VR ICD, VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Updates to the post sterilization test.
P980016/S591	06/14/2016	X - 30-Day Notice	MAXIMO II ICD D264DRM, D264VRM, D284VRC, D284DRG; PROTECTA ICD D334DRG, D334VRG, D334DRM, D334VRM; PROTECTA XT ICD D314DRG, D314VRG, D314DRM, D314VRM; SECURA ICD D204DRM, D204VRM, D224DRG, D224VRC; VIRTUOSO II DR/ VR ICD D274DRG, D274VRC	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update to the high voltage capacitor inspection requirements.
P980040/S069	06/17/2016	X - 30-Day Notice	TECNIS 1-PIECE IOL, TECNIS 1-PIECE OPTIBLUE IOL, PRELOADED TECNIS 1-PIECE IOL, PRELOADED TECNIS 1-PIECE OPTIBLUE IOL, PRELOADED TECNIC MULTIFOCAL 1-PIECE IOL, SENSAR 1-PIECE IOL, SENSAR ACRYLIC MONOFOCAL IOL	ABBOTT MEDICAL OPTICS INC	Expansion of the compressed air system.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980040/S070	06/27/2016	X - 30-Day Notice	SENSAR SOFT ACRYLIC INTRAOCULAR LENSES, TECNIS ACRYLIC INTRAOCULAR LENS, TECNIS ITEC PRELOADED DELIVERY SYSTEM.	ABBOTT MEDICAL OPTICS INC	Alternate sheet casting process.
P980043/S053	06/01/2016	X - 30-Day Notice	HANCOCK II PORCINE BIOPROSTHESIS	MEDTRONIC HEART VALVES	Modification of the stent machining process.
P990038/S021	06/08/2016	X - 30-Day Notice	ETI-MAK-2 PLUS ASSAY AND HBSAG CONFIRMATORY TEST ASSAYS	DIASORIN, INC.	Removal of an in-process washing step for a raw material and replacement with additional supplier and manufacturing controls.
P990041/S020	06/08/2016	X - 30-Day Notice	ETI-AB-EBK PLUS ASSAY	DIASORIN, INC.	Removal of an in-process washing step for a raw material and replacement with additional supplier and manufacturing controls.
P990042/S017	06/08/2016	X - 30-Day Notice	ETI-AB-AUK PLUS ASSAY	DIASORIN, INC.	Removal of an in-process washing step for a raw material and replacement with additional supplier and manufacturing controls.
P990043/S021	06/08/2016	X - 30-Day Notice	DIASORIN ETI-EBK PLUS ASSAY	DIASORIN, INC.	Removal of an in-process washing step for a raw material and replacement with additional supplier and manufacturing controls.
P990044/S018	06/08/2016	X - 30-Day Notice	ETI-CORE-IGMK PLUS ASSAY	DIASORIN, INC.	Removal of an in-process washing step for a raw material and replacement with additional supplier and manufacturing controls.
P990045/S018	06/08/2016	X - 30-Day Notice	ETI-AB-COREK PLUS ASSAY	DIASORIN, INC.	Removal of an in-process washing step for a raw material and replacement with additional supplier and manufacturing controls.
P990064/S062	06/01/2016	X - 30-Day Notice	MEDTRONIC MOSAIC PORCINE BIOPROSTHETIC HEART VALVE	MEDTRONIC HEART VALVES	Modification of the stent machining process.
P990080/S041	06/17/2016	X - 30-Day Notice	TECNIS ACRYLIC MONOFOCAL IOL	ABBOTT MEDICAL OPTICS INC	Expansion of the compressed air system.
P990080/S042	06/27/2016	X - 30-Day Notice	TECNIS 3-PCS MONOFOCAL LENS	ABBOTT MEDICAL OPTICS INC	Alternate sheet casting process.
P000030/S003	06/23/2016	X - 30-Day Notice	FOCUS NIGHT & DAY (LOTRAFILCON A) EXTENDED WEAR SOFT CONTACT LENSES	ALCON LABORATORIES, INC.	Qualification of two FTNIR instruments that are used for Betacon Macromer raw material incoming inspection quality control testing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P000053/S064	06/30/2016	X - 30-Day Notice	AMS 800 ARTIFICIAL URINARY SPHINCTER WITH INHIBIZONE TREATMENT	BOSTON SCIENTIFIC CORP.	Changes to the components and cleaning method of the equipment for the InhibiZone production line.
P010012/S421	06/20/2016	X - 30-Day Notice	DYNAGEN ¿ CRT-D: G150, G151, G154 DYNAGEN ¿ X4 CRT-D: G156, G158; INOGEN ¿ CRT-D: G140, G141 INOGEN ¿ X4 CRT-D: G146, G148	BOSTON SCIENTIFIC CORP.	Remove the final finish wetblast manufacturing process step.
P010012/S422	06/23/2016	X - 30-Day Notice	CONTAK CD, CONTAK RENEWAL, LIVIAN ICD FAMILIES; EASYTRAK, ACUITY SPIRAL LEAD FAMILIES; COGNIS, ENERGEN, INCEPTA, ORIGEN, INOGEN, DYANGEN CRT-D FAMILIES	BOSTON SCIENTIFIC CORP.	Alternate sterilization recipe and addition of a new sterilization release mechanism.
P010019/S051	06/23/2016	X - 30-Day Notice	FOCUS NIGHT AND DAY (LOTRAFILCON A AND B) EXTENDED WEAR SOFT CONTACT LENSES	ALCON LABORATORIES, INC.	Qualification of two FTNIR instruments that are used for Betacon Macromer raw material incoming inspection quality control testing.
P010030/S075	06/06/2016	X - 30-Day Notice	LIFEVEST WEARABLE DEFIBRILLATOR	ZOLL MANUFACTURING CORPORATION	Specification of a temperature controlled heat gun to be used in the LifeVest 4000 Electrode Belt Subassembly procedure.
P010030/S076	06/17/2016	X - 30-Day Notice	LIFEVEST WEARABLE DEFIBRILLATOR	ZOLL MANUFACTURING CORPORATION	Multiple changes including the addition of an automated test fixture, automation of specific test steps, expansion of test coverage to include the recently approved WCD model 4000B and correction of test limits used in service/ rework process.
P010031/S551	06/07/2016	X - 30-Day Notice	AMPLIA MRI CRT-D, AMPLIA MRI QUAD CRT-D, COMPIA MRI CRT-D,COMPIA MRI QUAD CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Updates to the post sterilization test.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S552	06/14/2016	X - 30-Day Notice	CONCERTO II CRT-D D274TRK, CONSULTA CRT-D D204TRM, CONSULTA CRT-D D224TRK, MAXIMO II CRT-D D264TRM, D284TRK, PROTECTA CRT-D D334TRM, D334TRG, PROTECTA XT CRT-D D314TRM, D314TRG;	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update to the high voltage capacitor inspection requirements.
P010032/S119	06/28/2016	X - 30-Day Notice	SPINAL CORD STIMULATION SYSTEM (GENESIS, ECO-C)IPG'S ; GENESIS, ECO, PROTEGE, PRODIGY) PATIENT PROGRAMMERS	St. Jude Medical	Change to the material used for the printed circuit board for the Genesic, Eon-C, Libra, and Libra XP Implantable Pulse Generators (IPGs), the Genesis and Eon/Protégé/Prodigy Patient Programmers, and the Libra and Brio Clinician Programmers.
P020004/S131	06/08/2016	X - 30-Day Notice	EXCLUDER BIFURCATED AAA ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Change in the radial placement of the catheter torque bump on the GORE® EXCLUDER® AAA Endoprosthesis SIM-PULL catheter.
P020056/S033	06/13/2016	X - 30-Day Notice	NATRELLE SILICONE-FILLED BREAST IMPLANTS	ALLERGAN	New style of pump to replace the pumps currently used to dispense silicone gel components from their storage drums into the mixing vessel.
P030005/S137	06/20/2016	X - 30-Day Notice	INGENIO¿ 2 CRT-P DEVICES; VALITUDE ¿ MODEL: U125; VALITUDE ¿ X4 MODEL: U128	GUIDANT CORP.	Remove the final finish wetblast manufacturing process step.
P030009/S087	06/15/2016	X - 30-Day Notice	INTEGRITY CORONARY STENT SYSTEMS	MEDTRONIC IRELAND	Add a manufacturing facility for the catheter subassembly.
P030017/S252	06/29/2016	X - 30-Day Notice	PRECISION NOVI SPINAL CORD STIMULATOR (SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Reduce the minimum time required for the Precision Novi IPG subassembly vacuum bake process.
P030053/S034	06/22/2016	X - 30-Day Notice	MEMORYGEL SILICONE GEL -FILLED BREAST IMPLANTS	MENTOR CORP.	Implementation of a multi-booth spray system for shell manufacture.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P040014/S030	06/24/2016	X - 30-Day Notice	THERAPY ABLATION CATHETER (INCLUDING BI-DIRECTIONAL) THERAPY 4MM THERMISTOR ABLATION CATHETER	IRVINE BIOMEDICAL, INC.	Acceptance to replace test equipment (RF generators) used for final inspection testing for the Therapy Ablation Series Catheters.
P040037/S092	06/07/2016	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Updates to supplier manufacturing equipment.
P040042/S035	06/24/2016	X - 30-Day Notice	THERAPY DUAL 8 THERAPY 8MM THERMISTER ABLATION CATHETER, SAFIRE TX BI-DIRECTIONAL ABLATION CATHETER	IRVINE BIOMEDICAL,INC.(IBI)	Acceptance to replace test equipment (RF generators) used for final inspection testing for the Therapy Ablation Series Catheters.
P040046/S015	06/13/2016	X - 30-Day Notice	NATRELLE HIGHLY COHESIVE SILICONE-FILLED BREAST IMPLANTS	ALLERGAN	New style of pump to replace the pumps currently used to dispense silicone gel components from their storage drums into the mixing vessel.
P040047/S043	06/27/2016	X - 30-Day Notice	COAPTITE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Modification of particle manufacturing process steps to eliminate a redundant test.
P050023/S099	06/24/2016	X - 30-Day Notice	VARIOUS MODELS OF SINGLE CHAMBER ICDS IN THE LUMAX, ILESTO, IFORIA, IPERIA, ITREVIA, INVENTRA FAMILIES, VARIOUS MODELS OF CRT-DS IN THE LUMAX, ILESTO, IFORIA, INVENTRA, IPERIA, ITREVIA FAMILIES	BIOTRONIK, INC.	Alternate supplier of the epoxy resin used in the device headers.
P050037/S071	06/23/2016	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Change in the calcium hydroxylapatite particle component manufacturing throughput.
P050037/S073	06/27/2016	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Modification of particle manufacturing process steps to eliminate a redundant test.
P050052/S083	06/23/2016	X - 30-Day Notice	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Change in the calcium hydroxylapatite particle component manufacturing throughput.
P050052/S085	06/27/2016	X - 30-Day Notice	RADIESSE (+) LIDOCAINE DERMAL FILLER	MERZ NORTH AMERICA, INC	Modification of particle manufacturing process steps to eliminate a redundant test.

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P060011/S009	06/08/2016	X - 30-Day Notice	C-FLEX MODEL 570C INTRAOCULAR LENS (IOL)	RAYNER INTRAOCULAR LENSES LTD.	Introduction of a new standard blister pouch for the Rayner C-flex 570C, C-flex Aspheric 970C and 600C Aspheric Intraocular lenses.
P060019/S037	06/24/2016	X - 30-Day Notice	THERAPY COOL PATH ABLATION CATHETER, THERAPY COOL PATH SP ABLATION CATHETER, SAFIRE BLU ABLATION CATHETER	IRVINE BIOMEDICAL, INC.	Acceptance to replace test equipment (RF generators) used for final inspection testing for the Therapy Ablation Series Catheters.
P060022/S023	06/23/2016	X - 30-Day Notice	AKREOS INTRAOCULAR LENS,MODEL AO60 AND MI60L	BAUSCH & LOMB, INC.	Addition of an alternative Fourier Transform Infrared Spectroscopy (FTIR) laboratory.
P060037/S045	06/01/2016	X - 30-Day Notice	ZIMMER NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Alternative belt dressing for metal finishing and polishing applications for the NexGen® LPS-Flex/LPS Mobile Bearing Knee System components.
P070008/S073	06/24/2016	X - 30-Day Notice	STRATOS LV/LV-T, EVIA/ ENTOVIS HF/HF-T, ELUNA/ ERINSA/EPYRA 8 HF-T CRT-PS	BIOTRONIK, INC.	Alternate supplier of the epoxy resin used in the device headers.
P070026/S036	06/17/2016	X - 30-Day Notice	CERAMAX CERAMIC TOTAL HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Change of a second-tier supplier of a raw material used in products of the CERAMAX® Ceramic Total Hip System.
P080006/S092	06/01/2016	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196,4296,4396 LEAD	MEDTRONIC INC.	Addition of a new crimper system used to crimp proximal connector components.
P080006/S094	06/24/2016	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Alternate supplier of the conductor coils.

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P080010/S013	06/27/2016	X - 30-Day Notice	TECNIS MULTIFOCAL FOLDABLE POSTERIOR CHAMBER INTRAOCULAR LENS (IOL)	ABBOTT MEDICAL OPTICS INC	Alternate sheet casting process.
P080011/S044	06/10/2016	X - 30-Day Notice	BIOFINITY (COMFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES	COOPERVISION MANUFACTURING, LTD.	Validation of Line 4 at the CooperVision Inc. Hamble, UK manufacturing facility to manufacture Biofinity Energys asphere minus power (plano to -12.00D, inclusive) and plus power (+0.25D to +8.00D, inclusive) lenses within the power ranges.
P080011/S045	06/09/2016	X - 30-Day Notice	BIOFINITY (COMFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES	COOPERVISION MANUFACTURING, LTD.	Removal of the osmolarity surveillance testing performed on the final packaged product.
P080025/S108	06/07/2016	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM (BOWEL)	MEDTRONIC NEUROMODULATION	Changes related to the under bump metallization (UBM) for the telemetry M module subcomponent of the impacted external device (model 3537).
P090006/S017	06/01/2016	X - 30-Day Notice	COMPLETE SE VASCULAR STENT SYSTEM - ILLIAC	MEDTRONIC VASCULAR	Changes to the stent manufacturing process.
P100009/S019	06/24/2016	X - 30-Day Notice	MITRACLIP NT CLIP DELIVERY SYSTEM	ABBOTT VASCULAR INC.	Add the option to sterilize the MitraClip NT Clip Delivery System (CDS) and Steerable Guide Catheter (SGC) at the existing alternate sterilization site.
P100013/S013	06/30/2016	X - 30-Day Notice	CORDIS EXOSEAL VASCULAR CLOSURE DEVICE	CORDIS CORPORATION	Transfer the indicator wire component's manufacturing process to an alternate manufacturing site.
P100017/S017	06/10/2016	X - 30-Day Notice	ABBOTT REALTIME HCV ASSAY, ABBOTT REALTIME HCV CALIBRATOR KIT, ABBOTT REALTIME HCV CONTROL KIT, ABBOTT MSAMPLE PREPARATION SYSTEM.	ABBOTT MOLECULAR, INC.	Relocation of manufacturing activities for the production of bulk reagents used for the Abbott mSample Preparation System.
P100017/S018	06/30/2016	X - 30-Day Notice	ABBOTT REALTIME HCV ASSAY	ABBOTT MOLECULAR, INC.	Change to bring reagent filling from an external supplier to an in-house process.
P100021/S052	06/16/2016	X - 30-Day Notice	MEDTRONIC VASCULAR ENDURANT STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Addition of an inspection step to the rear handle assembly process; 2) narrowing of the thread radius dimension tolerances on the handle lock; and 3) addition of detailed cleaning instructions at supplier for the moulding equipment.
P100021/S053	06/24/2016	X - 30-Day Notice	ENDURANT, ENDURANT II, ENDURANT II AORTO-UNI-ILIAC (AUI), ENDURANT IIS STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Relocation of certain stent graft material manufacturing process steps at an approved supplier.

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P100044/S021	06/17/2016	X - 30-Day Notice	PROPEL AND PROPEL MINI SINUS IMPLANTS	INTERSECT ENT	Modification of two packaging related processes: 1) the addition of an automated Desiccant Dispenser to automatically dispense the desiccants used in the manufacturing product packaging; and 2) the addition of a semi-automated Component Verification System for verifying the presence of components during packaging. These changes are being made to implement the addition of two new equipment systems to facilitate the conversion from manual to automated processes
P100047/S076	06/24/2016	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	HEARTWARE, INC.	Implementation of changes to the Splice Kit Assembly and the HVAD Large OD Sheath.
P110010/S126	06/16/2016	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM AND PROMUS PREMIER EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Introduce an alternate port mandrel manufacturing aid into the stent delivery catheter manufacturing process.
P110013/S069	06/10/2016	X - 30-Day Notice	RESOLUTE MICROTRAC/ RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Introduction of an optional chemical treatment into the manufacturing process for chloroform used in the drug/ polymer coating process of the Resolute Integrity stents at Medtronic Ireland.
P110013/S070	06/15/2016	X - 30-Day Notice	RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Add a manufacturing facility for the catheter subassembly.
P110013/S071	06/22/2016	X - 30-Day Notice	RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Implement an alternate control check for the Parylene coating process.
P110016/S032	06/14/2016	X - 30-Day Notice	FLEXABILITY ABLATION CATHETER (BI-DIRECTIONAL), (UNI-DIRECTIONAL)	ST. JUDE MEDICAL, INC.	Acceptance of a custom test fixture for confirmation of correct thermocouple in-process assembly for the FlexAbility manufacturing line.

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P110016/S033	06/24/2016	X - 30-Day Notice	COOL PATH DUO ABLATION CATHETER MEDIGUIDE ENABLED, AND SAFIRE DUO ABLATION CATHETER MEDIGUIDE ENABLED, THERAPY COOL PATH DUO SP ABLATION CATHETER AND SAFIRE BLU DUO SP ABLATION CATHETER, THERAPY COOL FLEX CATHETER	ST. JUDE MEDICAL, INC.	Acceptance to replace test equipment (RF generators) used for final inspection testing for the Therapy Ablation Series Catheters.
P110023/S019	06/22/2016	X - 30-Day Notice	EVERFLEX SELF-EXPANDING PERIPHERAL STENT SYSTEM (EVERFLEX)	MEDTRONIC VASCULAR INC	Changes to in-process product acceptance activities.
P110040/S009	06/01/2016	X - 30-Day Notice	COMPLETE SE VASCULAR STENT SYSTEM - SFA AND PPA	MEDTRONIC VASCULAR	Changes to the stent manufacturing process.
P120012/S013	06/10/2016	X - 30-Day Notice	ABBOTT REALTIME HCV GENOTYPE II, ABBOTT REALTIME HCV GENOTYPE II CONTROL KIT, ABBOTT MSAMPLE PREPARATION SYSTEM	ABBOTT MOLECULAR	Relocation of manufacturing activities for the production of bulk reagents used for the Abbott mSample Preparation System.
P120012/S014	06/30/2016	X - 30-Day Notice	ABBOTT REALTIME HCV GENOTYPE II ASSAY	ABBOTT MOLECULAR	Change to bring reagent filling from an external supplier to an in-house process.
P130005/S013	06/07/2016	X - 30-Day Notice	DIAMONDBACK 360 CORONARY ORBITAL ATHERECTOMY SYSTEM	CARDIOVASCULAR SYSTEMS, INC.	Use an alternate supplier for a component used to construct the OAS Pump.
P130006/S031	06/07/2016	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Updates to supplier manufacturing equipment.

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P130007/S015	06/01/2016	X - 30-Day Notice	ANIMAS VIBE SYSTEM	ANIMAS CORP.	Change to transfer the complaint return and investigation operations for the Dexcom G4 Platinum Sensors from the Dexcom facility in San Diego, California, to the Animas facility in West Chester, Pennsylvania. The Dexcom G4 Platinum Sensors are a component of the Animas Vibe System.
P130009/S059	06/10/2016	X - 30-Day Notice	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Changes to manufacturing aides and manufacturing specifications for the loader accessory.
P130019/S008	06/03/2016	X - 30-Day Notice	MAESTRO RECHARGEABLE SYSTEM	ENTEROMEDICS INC.	Changes to the software and hardware associated with the Rechargeable Neuroregulator (RNR) final assembly and circuit assembly test fixtures,
P130021/S021	06/21/2016	X - 30-Day Notice	MEDTRONIC COREVALVE (R) EVOLUT R SYSTEM	MEDTRONIC COREVALVE LLC	Removal of in-process tensile testing on the Flush Hub bond of the EnVeo R Delivery Catheter System.
P130026/S020	06/06/2016	X - 30-Day Notice	TACTICATH QUARTZ SET	St. Jude Medical	Changes to electrical tests performed during the TactiCath Quartz manufacturing process.
P130028/S007	06/08/2016	X - 30-Day Notice	ALGOVITA SPINAL CORD STIMULATION SYSTEM	ALGOSTIM, LLC	Changes to the workflow for the Clinician Programmer Printed Circuit Board manufacturing process.
P130028/S008	06/22/2016	X - 30-Day Notice	ALGOVITA SPINAL CORD STIMULATION SYSTEM	NUVECTRA CORPORATION	Use of an alternate polycarbonate/acrylonitrile butadiene styrene (PC/ABS) resin material to manufacture the lower housing of the Trial Cable Interface assembly.
P140009/S016	06/28/2016	X - 30-Day Notice	DEEP BRAIN STIMULATION SYSTEM (LIBRA, LIBRA XP) IPG'S; (LIBRA, BRIO) CLINICIAN PROGRAMMERS	ST. JUDE MEDICAL NEUROMODULATION	Change to the material used for the printed circuit board for the Genesic, Eon-C, Libra, and Libra XP Implantable Pulse Generators (IPGs), the Genesis and Eon/Protégé/Prodigy Patient Programmers, and the Libra and Brio Clinician Programmers.
P140010/S019	06/24/2016	X - 30-Day Notice	IN.PACT ADMIRAL PACLITAXEL-COATED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Alternate incoming analytical test procedure for the API.
P140028/S014	06/01/2016	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT SYSTEM	Boston Scientific Corporation	Supplier site change.
P140031/S017	06/10/2016	X - 30-Day Notice	EDWARD SAPIEN 3 TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Changes to manufacturing aides and manufacturing specifications for the loader accessory.
P150003/S014	06/16/2016	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	Boston Scientific Corporation	Introduce an alternate port mandrel manufacturing aid into the stent delivery catheter manufacturing process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150012/S005	06/15/2016	X - 30-Day Notice	INGEVITY LEADS	BOSTONSCIENTIFIC	Secondary supplier for the helix component.
P150012/S007	06/20/2016	X - 30-Day Notice	ESSENTIO VALITUDE¿ MRI: L110, L111, L131;PROPONENT VALITUDE¿ MRI: L210, L211, L231; ACCOLADE VALITUDE¿ MRI: L310, L311, L331	BOSTONSCIENTIFIC	Remove the final finish wetblast manufacturing process step.
P150012/S008	06/23/2016	X - 30-Day Notice	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Alternate sterilization recipe and addition of a new sterilization release mechanism.

Total: 127